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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.												
10/565,205	01/20/2006	Uri Amin	1454VASUS	9521												
David Klein Dekel Patent Beit HaRo'im 18 Menuha Venahala Street Room 27 Rehovot, 76209 ISRAEL	7590 07/17/2007		<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">SCHILLINGER, ANN M</td></tr><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td>3738</td><td></td></tr><tr><td>MAIL DATE</td><td>DELIVERY MODE</td></tr><tr><td>07/17/2007</td><td>PAPER</td></tr></table>		EXAMINER		SCHILLINGER, ANN M		ART UNIT	PAPER NUMBER	3738		MAIL DATE	DELIVERY MODE	07/17/2007	PAPER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/565,205

Applicant(s)

ARNIN ET AL.

Examiner

Ann Schillinger

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 6, 8-13, 15, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Layne et al. (U.S. Pub. No. 2002/0026195). Layne et al. discloses the following of claim 1: a spinal disc nucleus replacement comprising: an elastomeric sheath (50, 60) assembled around a rod (200, 210, 212, 213, 220), a portion of said sheath being arranged for sliding along said rod (see Figure 23); and a sheath compactor (275) adapted to slide a portion of said sheath along said rod from a first position to a second position (paragraph 0079), wherein in the first position said sheath is in a non-expanded orientation (see Figure 22) and in the second position said sheath is in an expanded orientation wherein folds of said sheath expand radially outwards from said rod (see Figures 23-25, 27). It should be noted that the examiner is interpreting the word “folds” to be any bend or winding that occurs on the outer boundary of the indicated sheath.

Layne et al. discloses the following of claim 2: the spinal disc nucleus replacement according to claim 1, wherein a stopper (265, 266) is at a distal portion of said rod and said

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sheath compactor is adapted to push a distal portion of said sheath against said stopper (see Figure 23; paragraph 0077).

Layne et al. discloses the following of claim 3: the spinal disc nucleus replacement according to claim 1, wherein a removable fastening ring (273) holds a portion of said sheath to said rod.

Layne et al. discloses the following of claim 5: the spinal disc nucleus replacement according to claim 1, wherein said rod is flexible (265 and 266 expand out; paragraph 0070).

Layne et al. discloses the following of claim 6: the spinal disc nucleus replacement according to claim 5, wherein said rod is flexed into an arcuate shape (paragraph 0010).

Layne et al. discloses the following of claim 8: the spinal disc nucleus replacement according to claim 5, wherein ends of said rod are fastenable together (paragraph 0070 indicates that the ends of 210 and 213 on the rod are fastened together and made integral).

Layne et al. discloses the following of claim 9: the spinal disc nucleus replacement according to claim 1, wherein said rod is withdrawable and removable from said sheath (paragraph 0010).

Layne et al. discloses the following of claim 10: the spinal disc nucleus replacement according to claim 1, wherein said folds of said sheath expand outwards generally uniformly (see Figure 23; paragraph 0085).

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Layne et al. discloses the following of claim 11: the spinal disc nucleus replacement according to claim 1, wherein said folds of said sheath expand outwards non-uniformly (see Figure 24, 25; paragraph 0085).

Layne et al. discloses the following of claim 12: the spinal disc nucleus replacement according to claim 1, wherein a distance between folds of said sheath varies axially along said rod (in Figures 23-25, an axis drawn along the rod would show that the right side of the sheath may be at a different distance from the rod than the left).

Layne et al. discloses the following of claim 13: the spinal disc nucleus replacement according to claim 1, wherein there are more folds on one side of said sheath than on another side of said sheath (see Figures 24, 25).

Layne et al. discloses the following of claim 15: the spinal disc nucleus replacement according to claim 1, further comprising a guiding wire (220) for introducing said sheath thereover (Figure 12).

Layne et al. discloses the following of claim 16: the spinal disc nucleus replacement according to claim 1, wherein said sheath is constructed of at least one of polyurethane, latex, natural rubber, silicone rubber, nylon, and shape memory polymer (paragraph 0086).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Layne et al. in view of Scholten et al. (U.S. Pat. No. 4,969,888). Layne et al. discloses the claimed invention except for a rod with a removable portion. Scholten et al. teaches a rod (30) with a removable portion (71) that allows various materials to be inserted into the intervertebral space without making additional incisions that will increase the chance of infection (col. 2, lines 11-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a rod with a removable portion that will allow several different materials to be inserted into the patient through one opening.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Layne et al. in view of Foley et al. (U.S. Pat. No. 6,676,665). Layne et al. discloses the claimed invention except for the rod being made of a shape memory material. Foley et al. in col. 9, lines 30-40, teaches a rod made of a shape memory alloy so that if the rod's shape is deformed when it is being used, it will return to its original shape and be available for use again. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a shape memory material when constructing the rod so that the instrument will maintain its original shape.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Layne et al. in view of Berger (U.S. Pat. No. 6,706,069). Layne et al. discloses the claimed invention except for an additional anchor to help hold the spinal disc nucleus replacement device in place. Berger teaches such a device in col. 5, lines 20-23 which will hold the spinal device in place while the

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patient is being treated. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use an additional anchoring device on the apparatus to prevent unnecessary movement while the apparatus is being used.

Response to Arguments

Applicant's arguments filed 4/25/2007 have been fully considered but they are not persuasive. Applicant contends that Layne et al.'s element 50 is not assembled around rod (200, 210, 212, 213, 220). However, the examiner is interpreting the term "around" from its dictionary definition, which states: "in a circular or rounded course" (around. Dictionary.com. Dictionary.com Unabridged (v 1.1). Random House, Inc. <http://dictionary.reference.com/browse/around> (accessed: June 25, 2007)). While the claim language does not specify that element 50 must surround the outside of the rod, the Layne et al. reference still reads on the claim as it goes around the inside of the disclosed rod element.

The Applicant further contends that Layne et al.'s element 275 is not "adapted to slide a portion of said sheath along said rod from a first position to a second position." Please note that the claim language "adapted to/for" is functional language. In order to be given patentable weight, a functional recitation must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language. *In re Fuller*, 1929 C.D. 172; 388 O.G. 279. Paragraph 0079 discloses that element 275 would be capable of sliding a portion of said sheath along said rod from a first position to a second position. Therefore, claims 1-16 stand rejected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger
June 25, 2007

A. Stewart
ALVIN J. STEWART
PRIMARY EXAMINER